

## Amendments to the Specification

**Page 8, lines 12-23, please rewrite as follows:**

### **Example 1**

300 g of MKC-242, 1500 g of D-mannitol (trade name: D-Mannitol, Kao Corporation), 900 g of hydrogenated oil (trade name: Lubri Wax 101, Kawaken Fine Chemicals. Co., Ltd.), 150 g of Microcrystalline cellulose (trade name: Avicel PH101, Asahi Chemical Industry Co., Ltd.) and 150 g of hydroxypropylcellulose (trade name: HPC-L, Nippon Soda Co., Ltd.) are placed into a stirring and mixing granulator (FS-GS-25J type, Fukae Kogyo) to mix them. Then, 390 g of water is added while mixing, followed by kneading. This kneaded material is granulated by extruding with a cylindrical granulator (HG-200 type, Hata Tekkoshio). A size of the resulting extruded granule is adjusted with Malmerizer (Q-230 type, Dalton Corporation), and the granule is placed into a fluidized bed granulating dryer (FLO-5M type, Freund Industrial Co., Ltd.) and is dried with a warm window wind at 70°C. 70°C.

**Page 8, lines 24-29, please rewrite as follows:**

Then, 1000 g of the resulting granule is placed into a rolling fluidized bed granulating dryer (MP-01 type, Powrex Corporation), and a coating solution obtained by adding 555 g of methacrylic acid copolymer LD (trade name: Eudragit L30D-55, Degussa), 17 g of triethyl citrate (trade name: Citroflex SC60, Morimura Bros., Inc.), 17 g of talc (Hayashi Kasei Inc.) and 555 g of water is sprayed thereto while blowing a warm wind at 60°C 60°C therein, to obtain a granule in which drug release is regulated.

**Page 8, line 30 to page 9, line 7, please rewrite as follows:**

### **Example 2**

300 g of MKC-242, 1500 g of D-mannitol (trade name: D-Mannitol, Kao Corporation), 900 g of carnauba wax (trade name: Polishing wax 103, Kawaken Fine Chemicals. Co., Ltd.), 150 g of Microcrystalline cellulose (trade name: Avicel PH101, Asahi Chemical Industry Co., Ltd.) and 150 g of hydroxypropylcellulose (trade name HPC-L, Nippon Soda Co., Ltd.) are placed into a stirring and mixing granulator (FS-GS-25J type, Fukae Kogyo) to mix them. Then, 390 g of water is added while mixing,

followed by kneading. This kneaded material is granulated by extruding with a cylindrical granulator (HG-200 type, Hata Tekkoshō). A size of the resulting extruded granule is adjusted with Malmerizer (Q-230-type, Dalton Corporation), and the granule is placed into a fluidized bed granulating dryer (FLO-5M type, Freund Industrial Co., Ltd.) and is dried with a warm wind at 70°C. 70°C.

**Page 9, lines 8-13, please rewrite as follows:**

Then, 1000 g of the resulting granule is placed into a rolling fluidized bed granulating dryer (MP-01 type, Powrex Corporation), and a coating solution obtained by adding 555 g of methacrylic acid copolymer (LD (trade name: Eudragit L30D-55, Degussa), 17 g of triethyl citrate (trade name: Citroflex SC60, Morimura Bros., Inc.), 17 g of talc (Hayashi Kasei Inc.) and 555 g of water is sprayed thereto while blowing a warm wind at 60°C 60°C therein, to obtain a granule in which drug release is regulated.

**Page 9, lines 14-25, please rewrite as follows:**

**Example 3**

300 g of MKC-242, 1500 g of D-mannitol (trade name: D-Mannitol, Kao Corporation), 900 g of stearic acid (trade name: Stearic Acid, Kao Corporation), 150 g of Microcrystalline cellulose (trade name: Avicel PH101, Asahi Chemical Industry Co., Ltd.) and 150 g of hydroxypropylcellulose (trade name: HPC-L, Nippon Soda Co., Ltd.) are placed into a stirring and mixing granulator (FS-GS-25J type, Fukae Kogyo) to mix them. Then, 390 g of water is added while mixing, followed by kneading. This kneaded material is granulated by extruding with a cylindrical granulator (HG-200 type, Hata Tekkoshō). A size of the resulting extruded granule is adjusted with Malmerizer (Q-230 type, Dalton Corporation), and the granule is placed into a fluidized bed granulating dryer (FLO-5M type, Freund Industrial Co., Ltd.) and dried with a warm wind at 70°C. 70°C.

**Page 9, lines 26-31, please rewrite as follows:**

Then, 1000 g of the resulting granule is placed into a rolling fluidized bed granulating dryer (MP-01 type, Powrex Corporation), and a coating solution obtained by adding 555 g of methacrylic acid copolymer LD (trade name: Eudragit L30D-55, Degussa), 17 g of triethyl citrate (trade name: Citroflex SC60, Morimura Bros., Inc.), 17 g of talc (Hayashi Kasei Inc.) and 555 g of water is sprayed thereto while blowing a warm wind at 60°C 60°C therein, to obtain a granule in which drug release is regulated.

**Page 9, line 32 to page 10, line 7, please rewrite as follows:**

**Example 4**

300 g of MKC-242, 1800 g of D-mannitol (trade name: D-Mannitol, Kao Corporation), 600 g of hydrogenated oil (trade name: Lovely Wax 101, Kawaken Fine Chemicals. Co., Ltd.), 150 g of Microcrystalline cellulose (trade name: Avicel PH101, Asahi Chemical Industry Co., Ltd.) and 150 g of hydroxypropylcellulose (trade name: HPC-L, Nippon Soda Co., Ltd.) are placed into a stirring and mixing granulator (FS-GS-25J type, Fukae Kogyo). Then, 390 g of water is added while mixing, followed by kneading. This kneaded material is granulated by extruding with a cylindrical granulator (HG-200 type, Hata Tekkosho). A size of the resulting extruded granule is adjusted with Malmerizer (Q-230 type, Dalton Corporation), and the granule is placed into a fluidized bed granulating dryer (FLO-5M type, Freund Industrial Co., Ltd.) and is dried with a warm wind at 70°C. 70°C.

**Page 10, lines 8-13, please rewrite as follows:**

Then, 1000 g of the resulting granule is placed into a rolling fluidized bed granulating dryer (MP-01 type, Powrex Corporation), and a coating solution obtained by adding 555 g of methacrylic acid copolymer LD (trade name: Eudragit L30D-55, Degussa), 17 g of triethyl citrate (trade name: Citroflex SC60, Morimura Bros., Inc.), 17 g of talc (Hayashi Kasei Inc.) and 555 g of water is sprayed thereto while blowing a warm wind at 60°C 60°C therein, to obtain a granule in which drug release is regulated.

**Page 10, lines 27-31, please rewrite as follows:**

**Experimental Example 1: Releasing test**

Regarding the granule obtained in Example 1, a releasing pattern was compared at the condition of 100 rpm and 37°C 37°C by a basket method (USP dissolution test method first method) using a 0.1 mol/L hydrochloric acid solution (pH 1.2) and a hydrochloric acid/trisodium phosphate buffer (pH 6.8).

**Page 11, lines 2-6, please rewrite as follows:**

On the other hand, regarding the conventional preparation obtained in Comparative example 1, a releasing pattern was studied at the condition of 50 rpm and 37°C 37°C by a paddling method using Japanese Pharmacopoeia first solution (pH 1.2)

and Japanese Pharmacopoeia second solution (pH 6.8). As a result, as shown in FIG. 2, approximate 100% was dissolved out in one hour in the conventional preparation.

**Page 11, line 18, Table 4, please rewrite as follows:**

| Dosage form           | C <sub>max</sub><br>(ng/mL) | T <sub>max</sub><br>(hr) | T <sub>1/2</sub><br>(hr) | AUC<br>(ng*hr/mL) | Adverse<br>events |
|-----------------------|-----------------------------|--------------------------|--------------------------|-------------------|-------------------|
| Example 1             | 202.4 $\pm$ 71.7            | 3.4 $\pm$ 0.7            | 11.9 $\pm$ 12.6          | 993 $\pm$ 242     | 0/6               |
| Comparative Example 1 | 431.8 $\pm$ 176.6           | 1.1 $\pm$ 0.6            | 2.9 $\pm$ 1.1            | 1110 $\pm$ 430    | 5/6               |